



10-04-04

Ifw

PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

		Application Number	10/750,138
		Filing Date	December 31, 2003
		First Named Inventor	David Gschneidner
		Art Unit	1616
		Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission	8	Attorney Docket Number	01946/100G527-US2

### ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	IDS Citation by Applicant and two references Certificate of Express Mailing
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application	Remarks	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	DARBY & DARBY P.C. Jason C. Chumney, 54,781
Signature	
Date	October 1, 2004



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# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

**TOTAL AMOUNT OF PAYMENT** (\$ 0.00)

Complete if Known	
Application Number	10/750,138
Filing Date	December 31, 2003
First Named Inventor	David Gschneidner
Examiner Name	Not Yet Assigned
Art Unit	1616
Attorney Docket No.	01946/100G527-US2

**METHOD OF PAYMENT (check all that apply)**
 Check  Credit Card  Money Order  Other  None

 Deposit Account:

Deposit Account Number **04-0100**

Deposit Account Name **Darby & Darby P.C.**

The Director is authorized to: (check all that apply)

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 Charge any additional fee(s) or any underpayment of fee(s)  
 Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

**FEE CALCULATION (continued)****3. ADDITIONAL FEES**

Large Entity	Small Entity	Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)
1051	130	2051	65 Surcharge - late filing fee or oath
1052	50	2052	25 Surcharge - late provisional filing fee or cover sheet.
1053	130	1053	130 Non-English specification
1812	2,520	1812	2,520 For filing a request for ex parte reexamination
1804	920*	1804	920* Requesting publication of SIR prior to Examiner action
1805	1,840*	1805	1,840* Requesting publication of SIR after Examiner action
1251	110	2251	55 Extension for reply within first month
1252	420	2252	210 Extension for reply within second month
1253	950	2253	475 Extension for reply within third month
1254	1,480	2254	740 Extension for reply within fourth month
1255	2,010	2255	1,005 Extension for reply within fifth month
1401	330	2401	165 Notice of Appeal
1402	330	2402	165 Filing a brief in support of an appeal
1403	290	2403	145 Request for oral hearing
1451	1,510	1451	1,510 Petition to institute a public use proceeding
1452	110	2452	55 Petition to revive - unavoidable
1453	1,330	2453	665 Petition to revive - unintentional
1501	1,330	2501	665 Utility issue fee (or reissue)
1502	480	2502	240 Design issue fee
1503	640	2503	320 Plant issue fee
1460	130	1460	130 Petitions to the Commissioner
1807	50	1807	50 Processing fee under 37 CFR 1.17(q)
1806	180	1806	180 Submission of Information Disclosure Stmt
8021	40	8021	40 Recording each patent assignment per property (times number of properties)
1809	770	2809	385 Filing a submission after final rejection (37 CFR 1.129(a))
1810	770	2810	385 For each additional invention to be examined (37CFR 1.129(b))
1801	770	2801	385 Request for Continued Examination (RCE)
1802	900	1802	900 Request for expedited examination of a design application
Other fee (specify)			

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3) (\$)**

\*\*or number previously paid, if greater; For Reissues, see above

SUBMITTED BY		(Complete if applicable)	
Name (Print/Type)	Jason C. Chumney	Registration No. (Attorney/Agent)	54,781
Signature		Date	October 1, 2004



Application No. (if known): 10/750,138

Attorney Docket No.: 01946/100G527-US2

## Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. \_\_\_\_\_ in an envelope addressed to:

MS Amendment  
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Alexandria, VA 22313-1450

EU 367698644-US

on October 1, 2004  
Date

B.W. Lee

Signature

B.W. LEE

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Transmittal Form (1 page);  
Information Disclosure Statement (2 pages);  
Fee Transmittal for FY 2004 (1 page);  
2 References  
List of References (PTO\SB08a\b form) (3 pages); and  
Return Receipt Postcard;



Docket No.: 01946/100G527-US2  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
David Gschneidner et al.

Application No.: 10/750,138

Confirmation No.: 9762

Filed: December 31, 2003

Art Unit: 1616

For: COMPOUNDS AND COMPOSITIONS FOR  
DELIVERING ACTIVE AGENTS

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)).

Those patent(s) or publication(s) which are marked with a double asterisk (\*\*) next to the Cite No. in the attached form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in a prior application number 10/168,275, filed July 15, 2002 and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

A copy of each Foreign patent document on the PTO/SB/08 not previously cited is attached (WO 96/30036 and WO 97/36480).

Copies of U.S. Patent documents that were not previously cited (U.S. 5,401,516 and U.S. 5,443,841) are not required, as this application was filed after June 30, 2003.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Commissioner is authorized to charge any deficiency or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: October 1, 2004

Respectfully submitted,

By \_\_\_\_\_

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Registration No.: 34,781

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PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/B/PTO				<b>Complete If Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				Application Number	10/750,138
Sheet	1	of	3	Filing Date	December 31, 2003
				First Named Inventor	David Gschneidner
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	01946/100G527-US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
AA**	US-5,776,888-B1		07-07-1998	Leone-Bay et al.	
AB**	US-5,629,020		05-13-1997	Leone-Bay et al.	
AC**	US-5,643,957		07-01-1997	Leone-Bay et al.	
AD**	US-5,766,633		06-16-1998	Milstein et al.	
AE**	US-5,863,944		01-26-1999	Leone-Bay et al.	
AF**	US-5,866,536		02-02-1999	Leone-Bay et al.	
AG**	US-5,650,386		07-22-1997	Leone-Bay et al.	
AH**	US-3,795,739		03-05-1974	Birkmayer et al.	
AI**	US-3,939,253		02-17-1976	Bodor et al.	
AJ**	US-4,061,466		12-06-1977	Sjoholm et al.	
AK**	US-4,147,767		04-03-1979	Yapel	
AL**	US-4,207,341		06-10-1980	Hubner et al.	
AM**	US-4,221,815		09-09-1980	Weyer et al.	
AN**	US-4,238,506		12-09-1980	Stach, deceased et al.	
AO**	US-4,239,754		12-16-1980	Sache et al.	
AP**	US-4,393,192		07-12-1983	Curatolo et al.	
AQ**	US-4,442,090		04-10-1984	Kakeya et al.	
AR**	US-4,499,299		02-12-1985	Bernstein et al.	
AS**	US-4,462,991		07-31-1984	Higuchi et al.	
AT**	US-4,656,161		04-07-1987	Herr et al.	
AU**	US-4,654,327		03-31-1987	Teng	
AV**	US-4,692,433		09-08-1987	Hostetler et al.	
AW**	US-4,757,066		07-12-1988	Shiokari et al.	
AX**	US-4,835,312		05-30-1989	Itoh et al.	
AY**	US-4,873,087		10-10-1989	Morishita et al.	
AZ**	US-4,878,942		11-07-1989	Motegi et al.	
AA1**	US-4,900,730		02-13-1990	Miyauchi	
AB1**	US-4,927,928		05-22-1990	Shroot et al.	
AC1**	US-5,066,487		11-19-1991	Morelle et al.	
AD1**	US-5,352,461		10-04-1994	Feldstein et al.	
AE1**	US-5,665,700		09-09-1997	Cho et al.	
AF1**	US-5,705,529		01-06-1998	Matyus et al.	
AG1**	US-5,447,728		09-05-1995	Milstein et al.	
AH1**	US-5,451,410		09-19-1995	Milstein et al.	
AI1**	US-5,541,155		07-30-1996	Leone-Bay et al.	
AJ1**	US-5,709,861		01-20-1998	Santiago et al.	
AK1**	US-5,714,167		02-03-1998	Milstein et al.	
AL1**	US-5,750,147		05-12-1998	Kantor et al.	
AM1**	US-Re 35,862		07-28-1998	Steiner et al.	
AN1**	US-5,792,451		08-11-1998	Sarubbi et al.	
AO1**	US-5,804,688		09-08-1998	Leone-Bay et al.	

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>				<b>Complete If Known</b>	
Sheet	2	of	3	Application Number	10/750,138
				Filing Date	December 31, 2003
				First Named Inventor	David Gschneidner
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	01946/100G527-US2

	AP1**	US-5,811,127	09-22-1998	Milstein et al.	
	AQ1**	US-5,876,710	03-02-1999	Leone-Bay et al.	
	AR1**	US-5,879,681	03-09-1999	Leone-Bay et al.	
	AS1**	US-5,939,381	08-17-1999	Leone-Bay et al.	
	AT1**	US-5,958,457	09-28-1999	Santiago et al.	
	AU1**	US-5,965,121	10-12-1999	Leone-Bay et al.	
	AV1**	US-5,989,539	11-23-1999	Leone-Bay et al.	
	AW1**	US-5,990,166	11-23-1999	Leone-Bay et al.	
	AX1**	US-6,001,347	12-14-1999	Leone-Bay et al.	
	AY1**	US-5,773,647	06-30-1998	Leone-Bay et al.	
	AZ1	US-5,401,516	03-28-1995	Milstein et al.	
	AA2	US-5,443,841	08-22-1995	Milstein et al.	
	AB2**	US-4,035,507	07-12-1997	Bodor et al.	

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear <sup>T<sup>6</sup></sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY		
BA**	EP0576941		01-05-1994		
BB**	EP0036145		09-23-1981		
BC**	EP0365183		04-25-1990		
BD**	EP0517211		12-09-1992		
BE**	EP226223		06-24-1987		
BF**	FR4446		11-02-1966		
BG**	GB2095994		10-13-1982		
BH**	JP2239980		09-21-1990		
BI**	JP4837819		11-14-1973		
BJ**	ES369853		07-16-1971		
BK**	WO8807378		10-06-1988		
BL**	WO9747270		12-18-1997		
BM	WO9630036		10-03-1996		
BN	WO9736480		10-09-1997		
BO**	WO9929705		06-17-1999		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\*CITE NO.: Those patent(s) or publication(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			<sup>T<sup>2</sup></sup>

Examiner Signature	Date Considered
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Substitute for form 1449A/B/PTO				<i>Complete if Known</i>	
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				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	3	of	3	Attorney Docket Number	01946/100G527-US2

CA**	Picciola G.: "Sintesi Di Acidi Chiazolinioici E Benzossazinonici E Studio Delle Loro Proprietà Antinflammatorie" IT, Societa Chimica Italiana Pavia vol 31, no. 9 pgs 655-664 and English Translation	
CB**	Chem Abs 73548-12-6 (4/1991)	
CC**	Chem Abs 70204-54-5 (4/1991)	
CD**	Chem Abs 184360 -83-342 (1975) "Solubility and disassociation constants of some alicyclic acids"	
CE**	Chemical Abstract, Vol. 99(23) Abst. No. 191473h (1983)	
CF**	Riveria, Theresa M. et al. "Oral Delivery of Heparin in Combination with Sodium N-[8-2-hydroxybenzoyl]amino]caprylate: Pharmacological Considerations" Pharmaceutical Research vol 14(12) 1830-1834 (1997)	
CG**	Leone-Bay, A. et al. "The evolution of an oral heparin dosing solution" Drugs of the Future vol 22(8) 885-891 (1997)	
CH**	Brayden, D. et al. "Heparin Absorption across the intestine: Effects of Sodium N-[8-2-hydroxybenzoyl]Amino] Caprylate in rat in situ intestinal instillations and in Caco-2 monolayers" Pharmaceutical Research vol 14(12) 1772-1779 (1997)	
CI**	Leone-Bay, A. "Acylated non-alpha-amino acids as novel agents for the oral delivery of heparin sodium, USP" Journal of Controlled Release 50: 41-49 (1998)	
CJ**	Leone-Bay, A. "4-[4-(2-Hydroxybenzoyl) amino]phenyl]-butyric Acid as Novel Oral Delivery Agent for Recombinant Human Growth Hormone"; Journal of Medicinal Chemistry vol. 39, no. 13 pp 2571-2578 (1996)	
CK**	Leone-Bay, A. "N-Acylated alpha-amino acids as novel oral delivery agents for proteins" ; Journal of Medicinal Chemistry vol 38, 4263-4269 (1995)	
CL**	Leone-Bay, A. "N-Acylated alpha-amino acids as novel oral delivery agents for proteins" ; Journal of Medicinal Chemistry vol 38, 4257-4262 (1995)	
CM**	Ho Koc-Kan; et al. "A Practical Synthesis of $\omega$ -aminoalkanoic acid derivatives from Cycloalkanones" Synthetic Communication, vol. 26, no. 14: 2641-2649 (1996)	
CN**	Gurrieri and Siracusa: "Thermal Condensation of Some alpha-aminoacids with Phthalic Acid" Thermochemical Acta, 7 (1973) 231-239	
CO**	Amino Yusuke et al. Chem Pharm Bull 36 pgs 4426-4434 (1988)	
CP**	Brown et al., J. Med. Chem. 27:79-81 (1984)	
CQ**	Johansen, Marianne, et al. "The Kinetics of decompr. Of various N-Mannich bases of salicylamide" Int. J. Pharm. (1980), 7(2): 119-27 (1980)	
CR**	Palagiano, F. et al. "Synthesis, stability and anticonvulsant activity of two new GABA prodrugs", PHARMAZIC, 52(d) : 272-276 (1976), XP-001084051	
CS**	Yalcin, I. et al. "Synthesis and Microbiological Activity of Some Novel N-(2-Hydroxyl-5-Substituted phenyl) Benzaacetatemides, Phenyl acetamides and Thiophenoxyacetamides as the Possible Metabolites of Antimicrobial Active Benzoxazoles," II Farmaco, 51(11), 685-681 (1977).	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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